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Dated: June 7, 2007

Signature: 

(Raymond W. Augustin)

Docket No.: OSTEONICS 3.0-380  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Wang et al.

Application No.: 10/071,667

Group Art Unit: 3733

Filed: February 8, 2002

Examiner: R. R. Shaffer

For POROUS METALLIC SCAFFOLD FOR  
: TISSUE INGROWTH

**APPEAL BRIEF**

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby file this brief on Appeal to appeal from the final rejection of claims 1-4, 6, 9-13, 15-18, 79, 82-87, 89-93, 95-98, and 101-103 mailed October 5, 2006.

**REAL PARTY(IES) IN INTEREST**

The real party in interest in this case is the assignee of record, Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, New Jersey 07430, as evidenced by the Assignments from Kathy Wang dated March 12, 2003 and recorded at reel 013926 frame 0646 and from Nicholas Dong and Michael Meehan dated June 27, 2002 recorded at reel 013464 frame 0685.

**RELATED APPEALS AND INTERFERENCES**

To the best of the current knowledge of Appellant, there are no related appeals or interferences pending before the United States Patent and Trademark Office regarding this United States Patent application.

**STATUS OF CLAIMS**

Claims 1-4, 6, 7, 9, 11-13, 15-18, 79, 82-87, 89, 91-93, 95-98, and 101-103 are pending in the present application. Claims 1, 6, 82, 84-87, and 95 are being appealed. A clean copy of the appealed claims are attached hereto as Appendix A.

**STATUS OF AMENDMENTS**

The most recent Amendment filed June 26, 2006 has been entered. An Amendment under 37 C.F.R. § 1.116 is filed herewith.

**SUMMARY OF CLAIMED SUBJECT MATTER**

The invention provides a porous metal scaffold for use in an implantable medical device comprising a porous metal network having pores defined by metal webs, the metal webs covered with at least one layer of metal particles bonded to the metal webs. Preferably, the metal webs of the porous metal scaffold may form a continuous inner skeleton. The pore size of the porous scaffold may be varied by bonding additional layers of metal particles to the at least one layer of particles. Also, changing a size of the metal particles may also vary the pore size of the porous scaffold. The metal foam is made by using a polyurethane foam and coating it with metal by chemical vapor deposition (CVD).

applied to thicken the green metal foam. The same goal may be accomplished by varying the particle size of the titanium powder. However, it should be understood that if the particle size of the powder is too large, the particles may not be able to penetrate into the pores of the metal foam.

In another illustrative non-limiting example, 1100  $\mu\text{m}$  pore size polyurethane foam may require two powder layers to produce 600  $\mu\text{m}$  pore size. Increasing the number of powder layers to three decrease the final metal pore size to approximately 400  $\mu\text{m}$ , while applying only one layer of powder would result in final pore size of approximately 800  $\mu\text{m}$ . The thickness and the required number of layers of the metal powder may be affected by the characteristics of the powder particle, such as average size, shape and particle size distribution.

Claims 1, 6, 82, 84-87, and 95 are being appealed.

Claim 1 relates to a porous biocompatible metal foam network having an open cell structure wherein the openings of each cell are formed by metal webs covered with at least one layer of metal particles disclosed in paragraph [0033]-[0039] of the application. At least some of the webs are covered with at least one layer of biocompatible metal particles having a size range between about 20 and about 100 micron as disclosed in paragraph [0112] of the application. The metal particles are bonded to the metal webs as discussed in paragraphs [0114] and [0115] of the application. This is accomplished by vacuum sintering as discussed in paragraph [0131] of the application. The porous metal network has a pore size of 100 to 100 microns and preferably 300 to 500  $\mu\text{m}$  as disclosed in paragraph [0029] of the application after sintering.

Claim 6 is similar to claim 1 as is supported by the specification as set forth in the paragraph immediately above, with the addition that the webs have partially hollow cores as discussed in paragraph [0018] of the application which hollow cores are surrounded by an outer web wall that has openings therein as discussed in [0107] of the application.

Claim 82 is directed to a metal scaffold for forming at least part of an implantable medical device as discussed in the abstract of the specification. The claim requires a porous biocompatible metal foam network having an open cell structure wherein the opening formed when a tissue contacting surface of the metal device as discussed in paragraphs [0023]-[0037] of the application. The claim contains the limitation that the metal webs are thicker on a side thereof (ID side) than a second side thereof (OD side) which is discussed in paragraphs [0103] and [0125] of the application.

Claim 84 requires at least one additional layer of metal particles be bonded to the first layer which is taught in paragraphs [0100] and [0101] of the application.

Claim 85 requires the metal particles to be between 20 micron and 100 micron in size. This is disclosed in paragraph [0028] of the application and also in paragraph [0114].

Claim 86 requires the web to have partially hollow cores. This is disclosed in paragraph [0018] of the application.

Claim 87 relates to the hollow cores having openings therein which is discussed in paragraph [0107]. Claim 95 relates to a porous metal scaffold having individual metal particles with a size of 40 microns to about 80 microns. This

size range is disclosed in paragraph [0114] of the specification.

GROUND'S OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 6, 82, 84-87, and 95 are anticipated by Kaplan U.S. Patent No. 5,282,861 under 35 U.S.C. § 102(b).

ARGUMENT

1. The rejection of claims 1, 6, 82, 84-87, and 95 under 35 U.S.C. § 102 over U.S. Patent No. 5,282,861. The Examiner rejects the claims as anticipated by the Kaplan reference apparently by assuming that the chemical vapor deposition process taught therein results in the same structure as claimed. Appellant wishes to point out that a chemical vapor deposition process uses vaporized metal for coating a substrate. The process involves depositing a solid material from a gaseous phase which results in a coating usually only a few microns thick. The Kaplan reference merely refers to the coatings as "thin films". The chemical vapor deposition process is not a line of sight process and therefore the vapor surrounds the webs and deposits the coating uniformly. The deposit of the metal is in the form of molecules of metal which Ultramet (the assignee of the Kaplan patent) refers to on their web site (copy attached as Appendix B) as the nanolayering at a rate of 100 to 400 microns per hour.

Claim 1 of the instant application distinguishes over the structure of Kaplan in that the metal webs as discussed in [0090] are formed by Low Temperature Arc Vapor Deposition (LTAVD) and are covered by at least one layer by metal particles

having a size range of between about 20 and 100 microns. This structure is similar to that formed by Kaplan with the CVD process. There are no particles utilized in Kaplan having a size greater than vaporized metal molecules which are able to only form a nanolayer inherent in vapor deposition. It can be seen that the particles claimed herein are a significant percentage of the desired pore size such that at least are one additional layers of particles (see claim 84) may be sintered to the claimed metal webs to reach the desired final pore size. It is Appellant's position that sintering, while a process step, results in particles which are sintered together to form a distinct structure. Sintering is defined as heating a metal powder which forms a coherent mass without melting. It is submitted that sintering is a term of art used in powder metallurgy for describing a structure formed by the welding together and growth of a contact area between two or more initially distinct particles at temperatures below their melting point but above 1/2 of the melting point (in Kelvins). Thus, the term bonding by vacuum sintering (claim 6) inherently claims a structure of sintered particles (bonded but not melted together) formed by the sintering process which structure, in combination with the metal webs, distinguishes over the structure of Kaplan. Kaplan has no particles bonded to the CVD metal webs and certainly not two or more layers (claim 84).

With regard to claim 6, Appellant has claimed that the metal webs are partially hollow with their hollow cores surrounded by metal webs with an outer web wall that has openings therein. This structure is not anticipated by Kaplan which does not have hollow web walls since, as taught therein, the metal is chemically vapor deposited on a carbon structure

which is solid. At the top of column 8 of Kaplan it states that FIG. 3 shows that each ligament is formed by a carbon core 104 covered by a thin film 106 of metal. The metal being deposited by CVD on the solid cores of Kaplan does not have openings therein but is solid as shown in the application and discussed in the process of depositing vapor on all sides of the carbon core. It should be noted that at the top of column 3 of Kaplan it states the disadvantages of using powder metallurgy to form a porous structure because some porous metallic materials, such as porous sintered powder-metallurgy materials, do not match the structure of cancellous bone sufficiently well to ensure successful ingrowth and integration. Although an obviousness rejection has not been made, this clearly teaches away from Appellant's process.

This disadvantage discussed in Kaplan has been overcome by Appellant's combination of metal webs formed by low temperature arc deposition covered by particles with the use of powder metallurgy to vary the pore size and roughen the surface.

With regard to claim 82, as corrected in the attached Amendment Under Rule 116, that as taught in paragraphs [0104] and [0126] of the application, the internal and external web surfaces can have different web thicknesses. As taught in Example 1 [0126], the increased web thickness would be on the side which contacts the substrate. Such a structure would not occur in Kaplan because, as taught in the materials taken from the Ultramet website, a key advantage of the CVD process lies in the fact that the reactants used are gases thereby taking advantage of the many characteristics of gases one of which is that the CVD process is not a line of sight process so that the

coatings deposited by CVD are conformable and near net shape. Thus, one would not obtain the claimed variation in thickness when using the process taught by Kaplan. There is no teaching in Kaplan of varying the thickness of the webs.

Kaplan does not teach or suggest using powder metallurgy to vary the porosity of a metal web which is hollow and has openings therein (claims 6 and 86). Kaplan does not teach varying the web thickness from one side of the scaffold to the other as claimed in claim 82. Kaplan uses a molecular vapor and not metal particles in the much larger size range claimed.

#### CONCLUSION

It is Appellant's position that the claims under appeal are not anticipated by Kaplan's structure which inherently results from an entirely different process than Appellant's. Appellants have claimed these differences between their structure and Kaplan in independent claims 1, 6 and 82. Since the single prior art reference relied upon by the Examiner, as an anticipation, must teach each and every element of Appellant's claims is submitted that the Examiner has not filled his burden in showing where the claim structural of Appellant's claims is identical to that taught in Kaplan.



Therefore, Appellant requests that the final rejection of the claims be overturned.

Dated: June 7, 2007

Respectfully submitted,

By 

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## APPENDIX A - CLAIMS

1. A porous metal scaffold for use in an implantable medical device comprising:

a porous biocompatible metal foam network having an open cell structure wherein the openings of each cell are formed by metal webs, at least some of the webs covered with at least one layer of biocompatible metal particles having a size range between about 20 and about 100  $\mu\text{m}$ , the metal particles being bonded to the metal webs wherein the bonding is accomplished by vacuum sintering the metal particles to said webs, the porous meal network having a pore size of 100 to 1000 $\mu$  for tissue ingrowth after sintering.

6. A porous metal scaffold for use in an implantable medical device comprising:

a biocompatible porous metal foam network having an open cell structure wherein the openings of each cell are formed by metal webs, at least some of the webs covered with at least one layer of biocompatible metal particles, the metal particles being bonded by vacuum sintering to the metal webs forming pores with a pore size of 100 to 1000 $\mu$  after sintering for tissue ingrowth wherein said webs have partially hollow cores wherein the hollow cores of said metal webs are surrounded by an outer web wall that has openings therein.

82. A porous metal scaffold forming at least a part of an implantable medical device comprising:

a porous biocompatible metal foam network having an open cell structure wherein the opening in each cell is surrounded by metal webs formed on a tissue contacting surface of the medical

device, the metal webs being thicker on a side thereof facing towards the tissue contacting surface, the webs covered with at least a first layer of biocompatible metal particles, the metal particles being bonded to the metal webs to produce a final cell opening size of between 100 and 1000 microns for tissue ingrowth.

84. The porous metal scaffold as set forth in claim 82 wherein at least one additional layer of metal particles is bonded to said first layer.

85. The porous metal scaffold as set forth in claim 82 wherein the size of the metal particles is between 20  $\mu\text{m}$  and 100  $\mu\text{m}$ .

86. The porous metal scaffold as set forth in claim 82 wherein said webs have partially hollow cores.

87. The porous metal scaffold as set forth in claim 86 wherein the hollow cores of said metal webs are surrounded by an outer web wall that has openings therein.

## APPENDIX B - EVIDENCE

APPENDIX C - RELATED PROCEEDINGS

None